TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDAAA Section of the 2007 amendments	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
222 [3]	3673	21,254	1	21,254	0.75	15,941
222 [2]	3673	2,162	1	2,162	0.50	1,081
222 [3]	3673	8,067	1	8,067	1	8,067
222 [3]	3673	1,305	1	1,305	0.25	326
223 [3]	3673	17,750	1	17,750	1	17,750
224 (waiver request) [2]	3673	14	1	14	1	14
224 (waiver request) [3]	3673	1	1	1	2	2
Total						43,181

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.
[3] Annual recurring burden.

TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN[1]

FDAAA Section of the 2007 amendments	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
222 [2]	23,806	1	23,806	0.25	5,952
223 [2]	11,746	4	46,984	0.5	23,492
Total					29,444

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Recurring burden.

Dated: January 9, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012–503 Filed 1–12–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0589]

Anneri Izurieta: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Anneri Izurieta for a period of 30 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Ms. Izurieta was convicted of six felony counts under Federal law for conduct relating to the importation into the United States of an article of food. Ms. Izurieta was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of November 4, 2011 (30 days after receipt of the notice), Ms. Izurieta had not responded. Ms. Izurieta's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective January 13, 2012.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, (301) 796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On May 11, 2011, in the U.S. District Court for the Southern District of Florida, Ms. Izurieta was convicted of one count of conspiracy to smuggle goods into the United States, in violation of 18 U.S.C. 371, and five counts of smuggling goods into the United States, in violation of 18 U.S.C. 545. The U.S. District Court for the Southern District of Florida entered judgment against Ms. Izurieta on July 29, 2011.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the importation into the United States of any food. The factual basis for these convictions is as follows: On or about April 18, 2007, and continuing through on or about December 23, 2010, in violation of 18 U.S.C. 371, Ms. Izurieta knowingly, and with the intent to further the object of the conspiracy, conspired with others to commit an offense against the United States to fraudulently and knowingly import and bring into the United States merchandise contrary to law in violation of 18 U.S.C. 545. Specifically, Ms. Izurieta conspired to distribute and sell imported dairy products that FDA had detained after receiving notice from FDA that the dairy products were suspected to be adulterated.

While serving as president and director of Naver Trading, Ms. Izurieta caused dairy products and other food to be imported from Honduras and Nicaragua. Despite a request from FDA to disclose the location of shipments of dairy products after learning that FDA had slated specific shipments for examination due to concerns of adulteration with *Escherichia coli,*

Staphylococcus aureus, and *Salmonella,* Ms. Izurieta failed to do so. Ms. Izurieta also distributed shipments of dairy products after learning that FDA had slated specific shipments for examination due to concerns of adulteration with *E. coli, S. aureus,* and *Salmonella.* Ms. Izurieta failed to redeliver for destruction and exportation shipments of dairy products that FDA had determined to be adulterated with *E. coli, S. aureus,* and *Salmonella* and that were not authorized for entry into the United States. Ms. Izurieta then distributed dairy products that were adulterated and not authorized for entry into the United States. This conduct was in violation of 18 U.S.C. 545.

From approximately April 18, 2007, and continuing to approximately December 7, 2010, Ms. Izurieta fraudulently and knowingly imported and brought into the United States merchandise contrary to law. Further, Ms. Izurieta failed to redeliver, export, and destroy with FDA supervision the dairy products and other food products contained in these shipments after receiving notice from FDA regarding concerns about the adulteration of these products with *E. coli, S. aureus,* and/or *Salmonella.*

As a result of her conviction, on September 28, 2011, FDA sent Ms. Izurieta a notice by certified mail proposing to debar her for a period of 30 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Ms. Izurieta was convicted of six felony counts under Federal law for conduct relating to the importation into the United States of an article of food because she conspired to and did commit offenses related to the importation of dairy products and other products into the United States, and a determination, after consideration of the factors set forth in section 306(c)(3) of the FD&C Act that Ms. Izurieta should be subject to the maximum possible period of debarment. The proposal also offered Ms. Izurieta an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Izurieta failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, and under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Ms. Anneri Izurieta has been convicted of six felony counts under Federal law for conduct relating to the importation of an article of food into the United States and that she is subject to the full period of debarment.

As a result of the foregoing finding, Ms. Izurieta is debarred for a period of 30 years from importing articles of food or offering such articles for import into the United States, effective (see **DATES**). Under section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Ms. Izurieta is a prohibited act.

Any application by Ms. Izurieta for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2011–N–0589 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 4, 2012.

Armando Zamora,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2012–542 Filed 1–12–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–M–0502, FDA–2011–M–0503, FDA–2011–M–0563, FDA–2011–M–0564, FDA–2011–M–0600, FDA–2011–M–0601, FDA–2011–M–0630, and FDA–2011–M–0707]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993–0002, (301) 796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2011, through September 30, 2011. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.